

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:
Epstein et al.

Application No.: 09/117,838

Examiner: Peselev, Eli

Filed: August 12, 1998

Group Art Unit: 1623

For: MEDICINAL PREPARATION

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

REPLY BRIEF

This paper is submitted in response to the Examiner's Answer mailed July 1, 2009, for the above-identified application, and addresses arguments that were set forth in the Examiner's Answer. Submission of a reply brief in response to the Examiner's Answer is due by September 1, 2009. Accordingly, this reply brief is being timely filed.

No fee is believed due in connection with this submission. If, however, any fee is due, such fee should be charged to Deposit Account No. 50-4711.

1. Status of the Claims

Claims 17, 19-21, 23, 25-27, 29-34 and 38-48 are pending, claims 1-16, 18, 22, 24, 28 and 35-37 were previously cancelled.

Claims 17, 19-21, 23, 25-27, 29-34 and 38-48 were finally rejected in an Office Action mailed on October 8, 2008. In an Amendment under 37 C.F.R. §1.116 to be filed subsequently to this Appeal Brief, Applicants will cancel claims 46-48 to facilitate the resolution of the issues in the present appeal. Accordingly, claims 17, 19-21, 23, 25-27, 29-34 and 38-45 are the subject of this appeal. Claims 46-48 are not addressed herein.

2. Grounds of Rejection to be Reviewed on Appeal

A. Whether claims 17, 19-21, 23, 25-27, 29-34 and 38-45 are anticipated under 35 U.S.C. § 102(b) by the prior art of record?

B. Whether claims 17, 19-21, 23, 25-27, 29-34 and 38-45 are obvious under 35 U.S.C. § 103 over the prior art of record?

3. Argument

A. Rejection of Claims 23, 25-27, 29-34 and 38-45 as Anticipated under 35 U.S.C. § 102(b)

It is respectfully submitted that the Examiner's Answer ignores the substance of Appellant's argument made in the Appeal Brief.

Thus, the Examiner states that a combination of a therapeutic dose and a homeopathic dilution of the same substance "would inherently result in a composition comprising said active ingredient in a therapeutic dosage." Examiner's Answer, at p. 6. In other words, the Examiner asserts that the substance disclosed in the cited prior art (*i.e.*, the active ingredient being in a standard therapeutic concentration) and the substance of a bipathic combination (*i.e.*, the substance that results from treatment of a therapeutic dose with a homeopathic dilution) are identical. However, the un-rebutted evidence contained within the file wrapper is directly contrary to the Examiner's allegation. For example, as described in more detail in the Appeal Brief, the *Epstein Declaration* filed with the paper of February 8, 2008 includes a comparison between several bipathic combinations and the corresponding standard therapeutic doses. The *Epstein Declaration* clearly establishes that treatment with homeopathic dilution significantly

modifies the properties of a therapeutic dose of the substance. This modification was shown across different groups of therapeutic substances, *in vitro*, *in vivo* and in a human clinical model.

The Examiner asserted that data contained in the file wrapper are deficient in that the declarations “do not provide in comparison form data showing how many experiments were conducted, what result was achieved by administration of an active substance at a therapeutic dosage and what effect was achieved by the claimed composition.” Examiner’s Answer, at page 6. Again, the data in the *Epstein Declaration* include numerous comparisons of properties of the claimed composition and the therapeutic dose and details of several specific studies. For example, the undersigned counsel respectfully directs the Board’s attention to the data set forth at pages 6-9. The data described on these pages of the *Epstein Declaration* are specific, baseline-controlled and the general methodology used to obtain the data is set forth in some detail. The evidence in the file wrapper establishes that the claimed combination and the substances disclosed in the prior art are different and have different properties.

It is further submitted that the scope of Applicant’s showing is sufficient to rebut a *prima facie* case of inherency even assuming, *arguendo*, that the Examiner met the burden of coming forward with such a *prima facie* case of inherency. The data in the file wrapper showed that at least for several distinct substances, the effect of modification of the standard dose with the homeopathic dilution is real and significant. The Appellant does not claim those bipathic combinations that do not exhibit modification in properties. The claims on appeal specifically recite only those combinations that exhibit “enhanced therapeutic properties in comparison with said active medicinal substance alone.” No evidence or reasoning could show that a substance disclosed in the prior art would have enhanced therapeutic properties in comparison with itself. Plainly, if any bipathic combination or substance does not possess such enhanced properties, it is not covered by the claims on appeal. Conversely, any prior art that does not disclose substances that possess such enhanced properties cannot anticipate the claims on appeal. The medicinal substances of the prior art, disclosed in standard therapeutic doses, clearly do not and cannot possess the claimed properties. It is therefore submitted that the scope of showing made by Appellant with respect to alleged inherency is fully commensurate with the scope of the claims.

Accordingly, Applicants submit that the rejection of claims 23, 25-27, 29-34 and 38-45 as anticipated under 35 U.S.C. § 102(b) cannot be sustained even on this basis alone.

B. Rejection of Claims 17 and 19-21 as Anticipated under 35 U.S.C. § 102(b) by the Prior Art of Record

According to the Examiner, the claimed methods encompass “nothing more than mixing the same active substance at different dosages resulting in a composition comprising an active substance at a therapeutic dosage.” Examiner’s Answer, at page 7.

Appellant respectfully direct board’s attention to the argument set forth in the immediately preceding section, which arguments are equally applicable herein.

On the basis of the foregoing, it is submitted that the rejection of claims 23, 25-27, 29-34 and 38-45 as anticipated under 35 U.S.C. § 102(b) cannot be sustained.

C. Rejection of Claims 23, 25-27, 29-34 and 38-45 as Obvious under 35 U.S.C. § 103 Over the Prior Art of Record

In the final Office Action, the Examiner did not articulate the reasoning related specifically to the obviousness rejection. The Examiner continued the same approach in the Examiner’s Answer. Specifically, the Examiner stated:

With respect to rejection of claim 23, 25-27, 29-34, and 38-45 as being obvious over the cited prior art, appellant contends that the prior art of record does not provide a reason to modify a therapeutic dose of a known pharmaceutical substance in the direction of the claimed bipathic medication. This argument has not been found persuasive since a combination of the same active substance at different dosage disclosed by the cited prior art would have been prima facie obvious to a person of ordinary skill in the art at the time of the claimed invention.

Examiner’s Answer, at page 7. In other words, the Examiner simply stated that the claims to bipathic combination are obvious but did not articulate any reason why it is so.

A finding of obviousness for a claimed combination of known elements requires a showing that “there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *KSR Int’l v. Teleflex, Inc.* 127 S. Ct. 1727, 1741 (2007). The prior art of record simply discloses several arbitrarily chosen medicinal substances at standard, therapeutic doses and does not provide any reason to modify the disclosed therapeutic dose in the direction of the claimed bipathic combination. Nor the prior art discloses anything related to homeopathic dilution, let alone their effect on substances from which they are produced. It is

respectfully requested that such effect is the essence of the invention claimed in the claims on appeal.

Appellant respectfully assert that the Examiner did not set forth a *prima facie* case of obviousness with respect to rejected claims. On the basis of the foregoing, it is submitted that the rejection of claims 23, 25-27, 29-34 and 38-45 as obvious under 35 U.S.C. § 103 cannot be sustained.

D. Rejection of Claims 17 and 19-21 as Obvious under 35 U.S.C. § 103 Over the Prior Art of Record

Appellant respectfully direct Board's attention to the argument set forth in the immediately preceding section, which arguments are equally applicable herein.

Further, as pointed out in the Appeal Brief and as again submitted herein, the rejected claim 17 includes a positive recitation of the steps "providing a homeopathic dilution of said active medicinal substance" and "admixing or incorporating said therapeutic dose and said homeopathic dilution with one another." Even if the homeopathic dose of a substance were completely subsumed in the therapeutic dose of the substance, a finding of obviousness would require that the prior art of record provide some disclosure of the recited steps at issue and/or an articulated to reasoning to modify the prior art. *KSR Int'l v. Teleflex, Inc.* 127 S. Ct. 1727, 1741 (2007).

Appellant respectfully assert that the Examiner did not set forth a *prima facie* case of obviousness with respect to rejected claims. On the basis of the foregoing, it is submitted that the rejection of claims 17 and 19-21 as obvious under 35 U.S.C. § 103 cannot be sustained.

CONCLUSION

Appellants submit that claims 17, 19-21, 23, 25-27, 29-34 and 38-45 meet the requirements for patentability under §§ 102 and 103. Accordingly, reversal of the Examiner's rejections is appropriate and is respectfully solicited.

Respectfully submitted,

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